PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Form PCT/IPEA/416
P/3881.WOP		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/EP2004/002703	16.03.2004	18.03.2003
International Patent Classification (IPC) or national classification and IPC		
A61B10/00		
Applicant		
WILLETT INTERNATIONAL LIMITED et al.		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 6 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☒ *sent to the applicant and to the International Bureau)* a total of 7 sheets, as follows:
      ☒ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the opinion
☐	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☒	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
16.01.2005	20.06.2005
Name and mailing address of the international preliminary examining authority:	Authorized Officer
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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/EP2004/002703

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
   - ☐ international search (under Rules 12.3 and 23.1(b))
   - ☐ publication of the international application (under Rule 12.4)
   - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

Description, Pages	
1-12	as originally filed
Claims, Numbers	
1-26	received on 24.01.2005 with letter of 16.01.2005
Drawings, Sheets	
1/1	as originally filed

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

* *If item 4 applies, some or all of these sheets may be marked "superseded."*

Box No. IV Lack of unity of invention

1. ☐ In response to the invitation to restrict or pay additional fees, the applicant has:
   - ☐ restricted the claims.
   - ☐ paid additional fees.
   - ☐ paid additional fees under protest.
   - ☐ neither restricted nor paid additional fees.

2. ☒ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

   ☐ complied with.

   ☒ not complied with for the following reasons:

   see separate sheet

4. Consequently, this report has been established in respect of the following parts of the international application:

   ☒ all parts.

   ☐ the parts relating to claims Nos. .

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-26
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-26
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-26
	No:	Claims	

2. Citations and explanations (Rule 70.7):

   see separate sheet

Section IV

The separate claimed inventions are:

1. A device including a first one of two marker ingredients provided in one or both of the layers and being adapted to interact with the body fluid such that a substance then migrates into the pad to interact therein with the second marker ingredient to generate the visible indication to allow for multiple interaction steps (claims 1-4)
2. A device wherein the marker ingredient(s) are incorporated into a slow release composition to extend the usage period of the device (claims 5-15)
3. A device further carrying colour filter material(s) to reduce the visual effect of extraneous components of the bodily fluid (claims 16-26)

Accordingly, special technical features of the claims, representing a contribution over the prior art as shown in D1, relate to those mentioned in the groups of claims listed above. The subject-matter of these groups of claims is not so linked as to form a single inventive concept (Rule 13.1 PCT), as there is apparently no technical relationship in the sense of Rule 13.2 PCT between these groups of special technical features or the corresponding technical problems solved.

Section V

1 Reference is made to the following document (D) cited in the International Search Report:

D1: WO 99/02985 A (ROSENGREEN LEA T) 21 January 1999 (1999-01-21)

2 Document D1 (p. 7, l. 21 to p. 8, l. 14; figs. 2, 3) discloses a device comprising a member (6, 20, 22) adapted to be worn upon the body of a mammal to receive bodily fluid and carrying a marker ingredient which is adapted to interact with a component of said fluid to generate a visible colour indication being characteristic of a medical condition (p. 7, ll. 31-34), wherein the member comprises a bodily fluid absorbent pad sandwiched between a bodily fluid permeable and an impermeable layer (fig. 3).

3 The subject-matter of claim 1 differs from this known device in that a first marker ingredient is provided in one or both of the layers and is adapted to interact with the body fluid such that a substance then migrates into the pad to interact with a second marker ingredient to generate the visible indication. The subject-matter of claim 1 is therefore novel (Article 33(2) PCT). The problem to be solved by the subject-matter of claim 1 is regarded as to allow visible detection of medical conditions requiring more than one separate reaction step by means of a layered pad device.

4 The subject-matter of claim 5 differs from this known device in that the marker ingredient(s) is/are incorporated into a slow release composition. The subject-matter of claim 5 is therefore also novel. The problem to be solved by the subject-matter of claim 5 is regarded as to extend the usage period of the device.

5 The subject-matter of claim 16 differs from this known device in that it further carries colour filter material(s). The subject-matter of claim 16 is therefore novel as well. The problem to be solved by the subject-matter of claim 16 is regarded as to further to reduce the visual effect of extraneous components of the bodily fluid.

6 The new features of claims 1, 5 and 16, respectively, are neither known from, nor rendered obvious by, the available prior art. Consequently, the subject-matter of claims 1, 5 and 16, and claims 2-4, 6-15, and 17-26 dependent thereon meets the requirements of Article 33 PCT.

With respect to claim 5, it is, however, to be noted that the relative terms "slow release" and "relatively lengthy period" have no well-recognised meaning and leave the reader in doubt as to the scope of the technical features to which they refer, thereby rendering the definition of the subject-matter of said claims unclear (Article 6 PCT).

Remarks

1 In claim 1, line 8, the term "interacting" should have been replaced by "which is

adapted to interact" (Article 6 PCT).

2 Independent apparatus claims should be drafted in the two-part form in accordance with Rule 6.3(b) PCT.

3 The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

4 Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in document D1 is not mentioned in the description, nor is this document identified therein.

5 The description should have been brought into conformity with the amended claims (Rule 5.1(a)(iii) PCT).

CLAIMS:

1. A device for non-invasively detecting or monitoring a medical condition in a mammal, said device comprising a member adapted to be worn upon the body of the mammal to receive at least some of a bodily fluid excreted by the mammal, said member carrying one or more marker ingredients which interact with one or more components of the bodily fluid to generate a colour or other visible indication, said interaction being characteristic of the medical condition in the mammal, wherein said member comprises a bodily fluid absorbent pad sandwiched between an inner, next to the body, bodily fluid permeable layer, and an outer bodily fluid impermeable layer, wherein said one or more marker ingredients comprises first and second marker ingredients, said first marker ingredient is applied to either or both of said inner and outer layers, and said second marker ingredient is applied to said absorbent pad, interaction of said bodily fluid with said first marker ingredient resulting in the migration into said absorbent pad of a substance which then interacts with said second marker ingredient to generate said colour or other visible indication.

2. A device according to claim 1 wherein said one or more marker ingredients are incorporated into a slow release composition so as to permit only progressive access of said bodily fluid to the marker ingredients thereby to provide detection or monitoring of said medical condition over a relatively lengthy period of time.

3. A device according to claim 1 or claim 2 wherein said member in addition to carrying said one or more marker ingredients also carries one or more colour filter materials to screen out or reduce the visual effect of extraneous components of said bodily fluid on said colour or other visual indication of said medical condition.

4. A device according to claim 1 or claim 2 or claim 3 wherein said member is adapted to be worn upon the body of a human to receive at least some of the urine excreted by the human.

5. A device for non-invasively detecting or monitoring a medical condition in a mammal, said device comprising a member adapted to be worn upon the body of the mammal to receive at least some of a bodily fluid excreted by the mammal, said member carrying one or more marker ingredients which interact with one or more components of the bodily fluid to generate a colour or other visible indication, said interaction being characteristic of the medical condition in the mammal, wherein said one or more marker ingredients are incorporated into a slow release composition so as to permit only progressive access of said bodily fluid to the marker ingredients thereby to provide detection or monitoring of said medical condition over a relatively lengthy period of time.

6. A device according to claim 5 wherein said member comprises a bodily fluid absorbent pad sandwiched between

an inner, next to the body, bodily fluid permeable layer, and an outer bodily fluid impermeable layer.

7. A device according to claim 6 wherein said one or more marker ingredients are applied to said inner layer.

8. A device according to claim 6 wherein said one or more marker ingredients are applied to the inner face of said outer layer, and are observable through said outer layer.

9. A device according to claim 6 wherein said one or more marker ingredients are applied to said absorbent pad.

10. A device according to claim 6 wherein said one or more marker ingredients comprises first and second marker ingredients, said first marker ingredient is applied to either or both of said inner and outer layers, and said second marker ingredient is applied to said absorbent pad, interaction of said bodily fluid with said first marker ingredient resulting in the migration into said absorbent pad of a substance which then interacts with said second marker ingredient to generate said colour or other visible indication.

11. A device according to claim 5 wherein said member comprises a bag or container worn by the mammal for collection of said bodily fluid.

12. A device according to claim 11 wherein said bag or

container includes a component through which or over which said bodily fluid passes in receipt by said bag or container, said one or more marker ingredients being applied to said component.

13. A device according to claim 11 wherein a tube feeds said bodily fluid to said bag or container, and said one or more marker ingredients are applied to the inner face of the tube and/or a component within the tube.

14. A device according to any one of claims 5 to 13 wherein said member in addition to carrying said one or more marker ingredients also carries one or more colour filter materials to screen out or reduce the visual effect of extraneous components of said bodily fluid on said colour or other visual indication of said medical condition.

15. A device according to any one of claims 5 to 14 wherein said member is adapted to be worn upon the body of a human to receive at least some of the urine excreted by the human.

16. A device for non-invasively detecting or monitoring a medical condition in a mammal, said device comprising a member adapted to be worn upon the body of the mammal to receive at least some of a bodily fluid excreted by the mammal, said member carrying one or more marker ingredients which interact with one or more components of the bodily fluid to generate a colour or other visible

indication, said interaction being characteristic of the medical condition in the mammal, wherein said member in addition to carrying said one or more marker ingredients also carries one or more colour filter materials to screen out or reduce the visual effect of extraneous components of said bodily fluid on said colour or other visual indication of said medical condition.

17. A device according to claim 16 wherein said member comprises a bodily fluid absorbent pad sandwiched between an inner, next to the body, bodily fluid permeable layer, and an outer bodily fluid impermeable layer.

18. A device according to claim 17 wherein said one or more marker ingredients are applied to said inner layer.

19. A device according to claim 17 wherein said one or more marker ingredients are applied to the inner face of said outer layer, and are observable through said outer layer.

20. A device according to claim 17 wherein said one or more marker ingredients are applied to said absorbent pad.

21. A device according to claim 17 wherein said one or more marker ingredients comprises first and second marker ingredients, said first marker ingredient is applied to either or both of said inner and outer layers, and said second marker ingredient is applied to said absorbent pad, interaction of said bodily fluid with said first marker

ingredient resulting in the migration into said absorbent pad of a substance which then interacts with said second marker ingredient to generate said colour or other visible indication.

22. A device according to claim 16 wherein said member comprises a bag or container worn by the mammal for collection of said bodily fluid.

23. A device according to claim 22 wherein said bag or container includes a component through which or over which said bodily fluid passes in receipt by said bag or container, said one or more marker ingredients being applied to said component.

24. A device according to claim 22 wherein a tube feeds said bodily fluid to said bag or container, and said one or more marker ingredients are applied to the inner face of the tube and/or a component within the tube.

25. A device according to any one of claims 16 to 24 wherein said one or more marker ingredients are incorporated into a slow release composition so as to permit only progressive access of said bodily fluid to the marker ingredients thereby to provide detection or monitoring of said medical condition over a relatively lengthy period of time.

26. A device according to any one of claims 16 to 25 wherein said member is adapted to be worn upon the body of

a human to receive at least some of the urine excreted by the human.